

**Privacy and Security Policy Workgroup  
Draft Transcript  
March 19, 2010**

**Presentation**

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Good afternoon and welcome, everybody, to the Privacy and Security Policy Workgroup. This is a federal advisory workgroup, and there will be opportunity at the end of the meeting for the public to make comments. Let me do a quick roll call of the members. Deven McGraw?

**Deven McGraw - Center for Democracy & Technology – Director**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Latanya Sweeney? Gayle Harrell?

**Gayle Harrell – Florida – Former State Legislator**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Paul Tang? Mike Klag? Judy Faulkner?

**Judy Faulkner – Epic Systems – Founder**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

John Blair? Paul Egerman?

**Paul Egerman – eScription – CEO**

Yes. Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Dixie Baker?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Yes, Dixie is there. Paul Uhrig?

**Paul Uhrig – SureScripts – Chief Privacy Officer, EVP Corporate Development**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Dave Wanser?

**Dave Wanser – NDIIC – Executive Director**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Kathleen Connor?

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Rachel Block? I believe she's coming in late. Laurel Stein? Terri Shaw?

**Terri Shaw – Children's Partnership – Deputy Director**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

John Houston?

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Joyce DuBow?

**Joyce DuBow – AARP Public Policy Institute – Associate Director**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Michael DePalo for Justine Handelman?

**Michael DePalo – BCBC**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Connie Delaney? Marianna Bledsoe?

**Marianna Bledsoe – NIH – Deputy Associate Director**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Peter Basch? Sue McAndrew?

**Sue McAndrew – HITSP – Deputy Director**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Jodi Daniel?

**Jodi Daniel – ONC – Director Office of Policy & Research**

Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Did I leave anybody off?

**Deven McGraw - Center for Democracy & Technology – Director**

Do we have Joy Pritts on?

**Joy Pritts – ONC – Chief Privacy Officer**

Yes, we do.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Good. Okay. Deven, we turn it to you.

**Deven McGraw - Center for Democracy & Technology – Director**

Great. Thanks.

**Sarah Wattenberg – ONCHIT – Public Health Advisor**

Sarah Wattenberg is also on.

**Deven McGraw - Center for Democracy & Technology – Director**

Sorry, Sarah.

**Sarah Wattenberg – ONCHIT – Public Health Advisor**

Thank you.

**Deven McGraw - Center for Democracy & Technology – Director**

I knew you were there. Thank you all very much. For those of you not in the D.C. area, we're having what might be the most beautiful day of the year, so I'm doubly appreciative of having your time today. We have some important things to cover, and I relooked at Judy's notice of the meeting that said it was a quick call. I'm not so sure how quick it will be, but hopefully it will be a very productive one and an efficient use of your time. Before we jump into the meat of what we're going to try to do today, I want to give you all an update on a couple of things, and then also set up a frame around the discussion and the straw man and why we came up with it and sort of where it sits within the spectrum of other work that's being done within the health IT policy committee workgroups, as well as at ONC.

First, an update: You'll recall that we spent some time on our last call. It's been a little while since we've been together talking about the need to tackle some, on a short-term basis, some more immediate security issues or identify some priorities with a small subset of our workgroup and perhaps some additional people. We have not done that yet, and the reason is because there are conversations that are going on now among the cochairs of the different, some of the Health IT Policy Committee workgroups where there is an enormous amount of overlap in terms of charge and responsibilities: the NHIN workgroup, us as the privacy and security workgroup, and the information exchange workgroup.

And to the extent that, in particular, the NHIN workgroup is beginning to delve down into details on technical requirements, which would include security for the NHIN Direct model, which will facilitate simple, one-to-one exchange of information among eligible providers and hospitals for meaningful use. That is likely to come on the table and need some immediate attention. And, to some extent, I'm sort of waiting for those discussions to flush themselves out a little bit more so that the agenda is a little bit more crystallized. So we haven't abandoned the idea of trying to proceed on multiple levels here because I think, in order to get the volume of decisions that will need to be made for stage one of meaningful use, in order to get them done, I don't think we have much of a choice but to try to be moving forward on multiple fronts. But again, it didn't make sense to me to sort of get some conversations started with some vague

notion of what might be helpful when I think it seems fairly clear that all of that should be a bit more crystallized over the next several weeks. Does anybody have any questions about that?

Great. Thank you very much. All right, so what then are we doing today? Well, clearly from the materials that we circulated to you all in advance, which is basically just a discussion outline, not slides, we're going to begin our conversation about consent, but really in a very targeted way, again to align with where the other workgroups are now focusing, and also issues that the ONC staff is grappling with because, you know, it's our sense that this will enable us to be relevant, quite frankly, and more helpful to these conversations while they are occurring versus, you know, setting forth our sort of agenda that might not necessarily be well connected with the work that the other workgroups are doing.

In other words, what the other workgroups that I mentioned are focusing on, and this would include the certification and adoption workgroup too for its piece of this, is really meaningful use of certified EHR technology and particular for stage one since it seems sooner than right around the corner. I mean, it's practically upon us, and insuring that the eligible professionals and hospitals that participate in the program have every opportunity to be successful in meeting meaningful use. And so, with respect to the exchange of health information for which consent is certainly quite relevant, this is a lot of the focus, at least in the more immediate term, is with respect to NHIN Direct, which involves the one-to-one exchange of information among providers pursuant to meaningful use. What I have labeled as sort of push, or some folks may consider it just a simple disclosure from one to another, consistent with meeting the terms of meaningful use.

At the same time, of course, there's also been the grant program for the state-based health information exchanges has started, and so while the Health IT Policy Committee is grappling with how to facilitate this direct exchange, there also needs to be considerations for what will be sort of the rules of the road with respect to participation in health information exchange as a noun or RHIOs. And so, you know, based on the latest meeting of the NHIN workgroup, which there was some information shared at the last policy committee that the sort of most immediate focus is on NHIN Direct, but a strong desire to also be moving forward on the state pieces. And I've just, I think, identified for you one of those areas where there's going to be some kind of division of responsibility for grappling with this among the existing workgroups that's still in the phase of being worked out. That is one of the sort of reasons why there's some sort of very specific conversations that we've laid on the table for your consideration today.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Deven....

**Deven McGraw - Center for Democracy & Technology – Director**

I think the other thing that needs to be said is that this conversation that we're having about consent, it may look like we're having it in a vacuum, and I think there's a potential in fact for these recommendations taken out of the context to look quite stark. And so one thing that I want to put for the group to either endorse or, of course, you can push back on me. But it's always been my sense that consent is a very important piece of privacy, but it's not the only thing that we have to consider. And, in fact, it's really part of a constellation of issues and a framework of protections for privacy and security, and so it's just one piece of a bigger pie. And so I wanted to make sure, particularly since we have the public on the phone today, that there's a clear understanding that these conversations that we're having today about consent should not be interpreted to mean that we think that consent is the only thing that is worth considering in privacy.

It is absolutely important, or we wouldn't be prioritizing it on our agenda, but it's, you know, we have a whole constellation of privacy issues to resolve, and a tentative work plan for getting there. And I just

wanted to make sure that we level set that again for the public, but also to have an opportunity for the workgroup to in fact endorse this notion that I know that I have certainly felt. And I cochair with Rachel, and we've had discussions with staff about this that this notion to that consent really fits within a framework of protections and it is not the only thing that we need to consider.

So before we get started talking about this, a couple of other, more administrative points to make. One is, we have what seems like a long call when you think about two hours at the beginning of it, but quickly deteriorates into less time than we need to sometimes talk about these thorny issues, so let's try to keep the conversation as focused on the issues we've put on the table today. We can certainly parking lot bigger picture things versus trying to take all of them on, on this call, and to try to be succinct in your points or even using the term ditto if you agree, just because I'm hearing from workgroup members that it's often hard to get your points in, which is a consequence of this being such a large group, but we think it's important to have multiple stakeholders at the table at the same time. And also, please don't forget to identify yourself before you speak.

And so, with that, I'm just going to pause there before we get started in talking about the straw man proposal that we've put on the table, which is very much a straw man, and forgive the gender reference. Our colleague, Micky Tripathi, uses straw dog, but I didn't want to put that in the document for fear that nobody would know what I was talking about. But it's just, you know, I find that our conversations flow better when we have a specific idea to talk about.

Again, this is in the context, as always, anything we say or do is just a recommendation to the policy committee, which then is either endorsed, rejected, modified by the policy committee and moved on to ONC. We don't have legal authority. That's the extent of what our tasks are, as always, on this workgroup. I'll pause to see if folks have reaction to what was not a very succinct framing, but I think I wanted to make sure that before we started this discussion that we had a little level-setting and that we were all essentially on the same, if not a similar page with respect to where this issue sits and the need to sort of focus on it, in the context of the work that the other workgroups are doing.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Deven, this is Kathleen Connor. I'd like to maybe kick this off noting that Dixie has raised some of these issues. If we're going to focus on NHIN Direct, I think it's incredibly important that we understand exactly what is going to be meant by that term. And, at this juncture, I understand that's still evolving.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

However, there seems to be, you know, the sense that it's very much like a HIPAA kind of transaction. It's a push, that there is a known receiver on the other end. That it may be the case that that push can be facilitated by an intermediary who, one would suppose, is not going to hold the information. Perhaps a clearinghouse, HIE entity, and that the main point of these transactions, the purposes would be for treatment, payment, and operation, although there are some new boundaries on that that have come out of HITECH, for example, the ability of a patient to request that out of pocket expenses not be sent to a payer. But I think that we need to understand those premises very clearly. Also, I'm concerned about multi-hop kinds of scenarios where, for example, if we say or if it's decided that NHIN Direct includes an intermediary, that there's not multiple intermediaries, and that we end up in a situation that we currently experience under HIPAA where it's not know who the intermediaries are and what their responsibilities are for the entities, the senders and receivers who have engaged them for that purpose.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Deven, this is John. I like those last comments. I just want to ask, do you feel that this one-to-one disclosure is the equivalent of a covered entity, the covered entity push or transfer of data?

**M**

Exchange.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. I mean, that's certainly my assumption, and I think we can make that assumption very clear as being a sort of catalyst for our recommendations if we need to. But the reason why I feel that way is because, again, it's based on those transactions that are covered by the meaningful use criteria, and are going to be fulfilled by EPs and hospitals, and which have sort of a limited circle of folks who will be exchanging and receiving information, all of which is sort of covered under the kind of HIPAA realm, arguably. But I see it as push, and I think we can be very clear about that. It certainly is personally where my comfort level – you know, it certainly was my assumption, our assumption in creating this.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Yes. I was more sticking to the disclosure piece of it because I think some people think of disclosures as when a request for disclosing documents to a non-covered entity comes into a provider, and they disclose that. That's not what this is.

**Deven McGraw - Center for Democracy & Technology – Director**

I don't think so.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Okay. All right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie Baker. Disclosure is well-defined in the HIPAA law, and it does include transfers of PHI between entities, whether the receiver be a covered entity or not.

**M**

Right, so this is not that.

**Deven McGraw - Center for Democracy & Technology – Director**

Right. I don't think it's that.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

That's why I brought it up because, as Dixie said, it covered a little more than what you mean by this.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is not....

**Deven McGraw - Center for Democracy & Technology – Director**

The scope of sort of push transactions that we're talking about here are limited to those two covered entities and not non-covered entities.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Right, I just wonder if disclosure, if we should use a different word, if that....

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**Jodi Daniel – ONC – Director Office of Policy & Research**

This is Jodi Daniel. Just to be clear, we did talk. In the straw proposal, it does say, or to a public health authority, which would not necessarily be a covered entity. They're obviously covered by other laws that require them to protect the data.

**Deven McGraw - Center for Democracy & Technology – Director**

Good point.

**Jodi Daniel – ONC – Director Office of Policy & Research**

It isn't simply that limited.

**Terri Shaw – Children's Partnership – Deputy Director**

This is Terri Shaw. To further muddy the water here, the discussion here is limited to eligible providers and hospitals for purposes of meaningful use.

**M**

Right.

**Terri Shaw – Children's Partnership – Deputy Director**

...conceptually what we're talking about. However, some meaningful use disclosures will be to non-eligible providers, in other words, not meaningful users in the receiving incentive sort of sense. The clearest example is a primary care provider who has got a patient who is moving into a long-term care facility, and they want to do coordination of care, summary of care information to that long-term care provider. The long-term care provider is most definitely not an eligible provider, but I think that's the type of disclosure that we're talking about here, right?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

That's a good definition, actually. I would move that we adopt what she just said, that it's from one of these eligible professionals or hospitals to another entity for the purpose of meaningful use.

**Michael DePalo – BCBC**

This is Mike DePalo. Am I to further understand that if it's in the context of the meaningful use, it's not only eligible providers and hospitals, but it's also EHR generated push transactions?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**M**

Yes.

**Michael DePalo – BCBC**

Okay.

**Terri Shaw – Children's Partnership – Deputy Director**

This is Terri Shaw again. This is my other question. If I'm reading this correctly though, what we're basically saying is what you're doing in this case, and we're busy defining what the case is, but the

bottom line is, whatever it is we're defining, the point is, it's just like current law. There's nothing new or different about it.

**Deven McGraw - Center for Democracy & Technology – Director**

That's absolutely right.

**M**

Yes.

**Terri Shaw – Children's Partnership – Deputy Director**

So to a certain extent, it doesn't really matter how much refinement of all this we do because the point is, current law.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

There is one issue. This is Kathleen again. That it's in current law, those transactions aren't simply a push transaction. Typically there's a request. There can be a request from a receiver to the sender for a particular piece of information, so is that being carved out of this?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

But the response is still a push.

**Deven McGraw - Center for Democracy & Technology – Director**

The response is still a push. Let me stop this for a second because we're getting well into the meat of this, which is terrific, but I want to make sure that, because it's possible that members of the public have not had a chance to see what's on the table, and so I'd like to basically summarize it to make sure that we're all aware of what we're talking about here. And that is, what we've put on the table is essentially what we're doing is taking something off of the table for our consent discussions, which is that eligible providers and hospitals that are engaging in one-to-one, and I'll already substitute the word pushes of data pursuant to stage one requirements of meaningful use, not be required to satisfy any additional prior patient authorization requirements beyond those that already exist in law or that the EP or hospital may adopt, as a matter of organizational or institutional policy.

Then I added a transparency point here that, of course, these eligible providers and hospitals should be, in fact, transparent with patients about data access, use, and disclosure, especially when data is disclosed outside the organization or entity. Then we went through a whole lot of bullet points for the rationale for why we could reach some, why we might be able to reach some level of comfort with saying that, you know, we're not going to impose any additional consent requirements beyond what exists in current law, and the most important of which, I think, is that, again, if you envision these as push transactions where the data is still under the control of the data holder, and is being pushed out, whether it's by request, but at a minimum, the provider data holder is making a decision, both about whether to push it, to whom to push it, how much information should be included there.

It's covered by existing law, and it's also arguably within patient expectation. It's not beyond what a patient would expect, for example, if they get referred to another healthcare provider that the data, that relevant data related to their treatment is going to go to another healthcare provider. So I'm going to stop there. There's a lot of other rationale in here, but we were having a good discussion, and I hated to interrupt it. But I wanted to make sure members of the public were aware of what was on the table.

**Paul Eggerman – eScription – CEO**

This is Paul Eggerman.



**Gayle Harrell – Florida – Former State Legislator**

Gayle has a word to say also.

**Deven McGraw - Center for Democracy & Technology – Director**

You're right in there, Gayle, after Paul.

**Paul Egerman – eScription – CEO**

I just had a couple questions. First, when you gave that summary, Deven, which was excellent, you said something like pursuant to like something about meaningful use. And I was confused by that, the coordination of call fall under that category. I mean, the main reason, like my medical record might be shared with, say, a specialist to coordinate care. Does that come under meaningful use? I just didn't understand that sort of phrase that you said about pursuant to....

**Deven McGraw - Center for Democracy & Technology – Director**

Well, I think it does, and when I use the term "pursuant to", I meant in order to fulfill the criteria of meaningful use, which includes sharing clinical summaries, incorporating lab data. There's that whole laundry list that's in the proposed rule.

**Paul Egerman – eScription – CEO**

Yes. Then also I think this is ... a couple of questions ... talking about hospitals, but you keep saying EPs, eligible providers ... definition.

**Deven McGraw - Center for Democracy & Technology – Director**

Right.

**Paul Egerman – eScription – CEO**

But you could be sharing between a provider who is eligible and one who isn't because....

**Deven McGraw - Center for Democracy & Technology – Director**

Well, that's right. That's right. I think what we're trying to get at is whether – again, it's a pretty narrow recommendation, and it's related to whether EPs and hospitals themselves would have to get consent in order to push data to meet meaningful use in stage one. And sometimes that means that means that the data is going to go to another covered entity. And as what appropriately pointed out, sometimes it's going to go somewhere else like a long-term care facility or a public health authority. But just for those transactions that are required to happen in order for the provider to meet meaningful use.

**Paul Egerman – eScription – CEO**

The other issue I have is I'm a little concerned about the expression of pushing data because one of the questions I heard from somebody. I missed the person's name. They said, well, what happens if somebody requests it. But if somebody requests it, then the answer is yes. That's not really a push. In other words, if my physician or a physician requests something of my primary care provider, and the primary care provider gives it, that's not the same as a push. That just means they asked for the data, and they got it.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

That's typically a request response. This is Kathleen.

**M**

It depends on if you're saying request for response from an exchange in the middle, outside of the provider's database and practice or from the provider.

**Paul Eggerman – eScription – CEO**

In other words....

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie. I would say it is a push because it's asynchronous. They have to first request it, but the response is a push.

**M**

Yes, but, Dixie, you make a distinction between a request response from an exchange versus a practice.

**Paul Eggerman – eScription – CEO**

Right. Anyway, this is Paul Eggerman.

**Deven McGraw - Center for Democracy & Technology – Director**

Let me let Paul finish his point.

**Paul Eggerman – eScription – CEO**

Yes. I mean, I think the distinction we're making that's an important one is between, it's really an exchange that we call it NHIN Direct. In other words, exchange between two providers or provider organizations. That's where the exchange is. And the category we're talking about, another way to define NHIN Direct is that there's no intermediary involved that has or is retaining a copy of the medical record.

**M**

I think that's right.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, I think that's right too, although I don't know that, again, since meaningful use is not just limited to eligible providers and hospitals sharing data amongst one another, but is in fact, you know, there will be some data sharing transactions that will need to occur under meaningful use that are not just between eligible. I'm quibbling with that piece of it, but I certainly was consistent with the latter point that you made.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie again. The meaningful use also includes reporting measures to CMS, which is not between to providers.

**Deven McGraw - Center for Democracy & Technology – Director**

That's right. I think we've identified that it's not just....

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Let me finish, please. It also includes transactions between or exchanges between a provider and a payer, and between a provider and public health. So it's not always between providers.

**Paul Eggerman – eScription – CEO**

That's a good comment, Dixie. This is Paul Eggerman again. But the best – the point I'm trying to make is I think the terminology of push is a little confusing, but the real issue is, when you think about it in terms of

an intermediary. Is there an intermediary involved that has or retains a copy of the record? If the answer is no, then that's the NHIN Direct model, and that's what we're really talking about in this discussion. The next discussion is when you have some intermediary that actually has a copy of the record for one reason or another.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

So it's like ... forward thing where it just takes it and takes it. It receives it and sends it someplace else.

**Paul Eggerman – eScription – CEO**

Yes. Basically, to the extent that there's any intermediaries, they're like letter carriers. They deliver the message without opening it.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. That's the problem for current clearing houses. They have to open the X12 transaction in order to find out where to route it, and they get PHI. And if you don't have a business partner relationship, a business specific relationship with them, then there's no accountability, so ... without some precaution.

**Deven McGraw - Center for Democracy & Technology – Director**

Let me let Gayle in here.

**Gayle Harrell – Florida – Former State Legislator**

This is exactly the point that I have a major concern about, especially if the patient doesn't know that that intermediary is there.

**Deven McGraw - Center for Democracy & Technology – Director**

Right.

**Gayle Harrell – Florida – Former State Legislator**

There needs to be disclosure to the patients if this information is going to be transmitted electronically. They, at that point, and they need to know if it's not a direct push, one provider to another provider, if it's going through an exchange because, at that point, the patient gets very nervous about it.

**M**

Wait. What about on a fax?

**Gayle Harrell – Florida – Former State Legislator**

A fax is a direct.

**W**

It goes directly.

**M**

Right, but there's an intermediary there, and there can be other intermediaries on a direct push that don't hold the PHI.

**Deven McGraw - Center for Democracy & Technology – Director**

Right, but I think we were beginning to, or at least I found it. We were beginning to coalesce, or at least I was finding appeal in Paul Eggerman's point that what we're talking about is that there isn't the presence

of an intermediary that has or retains a copy of the record. I'd like to parking lot the clearinghouse issue because I want to learn a little bit more about that.

But again, the assumption is that we're talking about the data holder that is an eligible professional or a hospital, which has control over where they're sending data, including the ability to say no to a request if they don't believe that it's appropriate to send the data. But just this notion, and if push is the wrong term, we'll think of another one. But this idea that the data is being sent or exchanged, is being done consistent with meaningful use requirements, so we know the universe of transactions we're talking about. There's not an intermediary in the middle that can retain the data, and are we comfortable that we're not, at this stage, going to require any additional consent requirements beyond, again, what is already in existence in current law, which these providers and hospitals ought to be familiar with.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**

Deven, it's Joyce. I have a question about that in terms of what you mean here by should be transparent for the patient. Does should mean that it would be nice, or should means must?

**Deven McGraw - Center for Democracy & Technology – Director**

That's a good question, Joyce. And I did add a transparency point in the straw man. When I first started to draft this, I had a vision in my head of a patient in an interaction with their doctor. A decision is made that the patient needs to go see a specialist, and they make the – you know, and so the patient either knows who the specialist is that's chose, and so there's some ... expectation, and some might even argue implied consent, even if it's not expressly given, that in fact....

**Joyce DuBow – AARP Public Policy Institute – Associate Director**

Yes, that one is easy.

**Deven McGraw - Center for Democracy & Technology – Director**

But that is easy.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**

But the ones that don't involve, like a referral, where the patient is not necessarily aware of the processes that happen in terms of the exchange, then the patient is not going to know.

**Deven McGraw - Center for Democracy & Technology – Director**

Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

The patient needs to know.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**

I agree, and I think....

**M**

But what are those?

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. I'd like to get in the queue.

**Deven McGraw - Center for Democracy & Technology – Director**

Sure. John first, then Kathleen.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

I'm just curious, in clinical practice, what those are, those examples.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**

Why does it have to be clinical practice if we're talking about an intermediary, so it means it's going....

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

No, an intermediary is charged with securely moving it from one side to the other, and that intermediary will have to be a business associate.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

You can, in law, make sure that they cannot open and look at that. I mean, they would be breaking the law if they were not supposed to be doing that. And I certainly understand consent if they're going to hold that in those pieces. But I'm asking, in clinical practice, when you say a referral is easy, when is a physician sending information to another physician on a patient when it's not about their treatment.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Public health reporting.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

But we're talking about between physicians, I thought.

**Deven McGraw - Center for Democracy & Technology – Director**

No, we're talking about any transaction that is required for meaningful use, which is not just treatment. A lot of it is treatment related ... coordination.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Okay, but I mean....

**Joy Pritts – ONC – Chief Privacy Officer**

Deven, would it help? This is Joy. Would it help to break down the discussion by for treatment and manage ... public health?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

And payments.

**Joy Pritts – ONC – Chief Privacy Officer**

And payments, just address them separately?

**Deven McGraw - Center for Democracy & Technology – Director**

Well, I'm assuming by public health that we're meaning transactions that are authorized by law.

**Joy Pritts – ONC – Chief Privacy Officer**

Right.

**Deven McGraw - Center for Democracy & Technology – Director**

For which today patients are not required to consent, so I'm a little concerned about breaking those up into pieces and going down the hole of consent for public health, which raises a lot of other issues.

**W**

But what about reporting for quality?

**Deven McGraw - Center for Democracy & Technology – Director**

Right.

**W**

That's part of meaningful use.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

The topic was transparency.

**W**

Right, well, it's transparency to patients.

**Deven McGraw - Center for Democracy & Technology – Director**

Transparency. Okay. Thank you. Thank you, Dixie. Let me see if we can at least take something definitively off the table here or define it a little more clearly, which is to say....

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Deven, this is Kathleen. I'd really like....

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. It's no problem. Just give me a second, and then you're next.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Okay.

**Deven McGraw - Center for Democracy & Technology – Director**

What we're talking about with push or whatever better term we want to use is that there is not an intermediary in the middle like a RHIO or an HIE or a network that has or retains a copy of that record. That the role of any intermediary would be limited to just moving the data from one place to wherever it goes. That in other words, when we're thinking about taking consent off the table, that's the frame in which we're looking at it. There's not that intermediary that I totally agree with everyone on this call, raises a lot of difficult questions. Kathleen?

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Thank you. My concern is that this is beyond the narrow meaningful use. When we talk about meaningful use transactions, those also include, I believe, transactions that could be to marketing. It could be to researchers. It could be to social security or an insurer because there's nothing that precludes that from happening under meaningful use. And all of those kinds of transactions that do require either authorization or consent, so we need to know that there are some capabilities that we expect the EHR technologies to support, even within the narrow confines of what you're describing. I would also say, it's problematic when we keep talking about one intermediary. There may be multiple intermediaries. And I think one of the ... should be that these intermediaries should only have access to routing information and no PHI because that is a critical issue for consumers, as has been pointed out. Thank you.

**Deven McGraw - Center for Democracy & Technology – Director**

Thanks, Kathleen. There's sort of a host ... we're definitely not trying to change current law here.

**Terri Shaw – Children's Partnership – Deputy Director**

Yes. This is Terri. Can I jump in on that?

**Deven McGraw - Center for Democracy & Technology – Director**

Yes.

**Terri Shaw – Children's Partnership – Deputy Director**

That kind of to me is the underlying point. That what we're talking about here are, what we're saying are, these meaningful use disclosures, whoever they may be going to, the mere fact that they are electronic in nature does not affect the underlying law and all the rules that apply, including rules for authorization in some cases, and no authorization, nor consent of any kind, in other cases. So the mere fact that it's electronic does not change underlying law.

**Deven McGraw - Center for Democracy & Technology – Director**

That's right.

**Terri Shaw – Children's Partnership – Deputy Director**

But what we're next going to get into a policy discussion on, I believe, is in those cases where, by virtue of engaging in health information exchange in a way that involves intermediaries that do have access to or retain information that is protected, then we have changed the nature of what's going on. Therefore, there is a need to clarify the policy there, but lacking that extra entity that it changes the nature of the disclosure really because it involves somebody else receiving and retaining that information. Absent that, currently law is what we're talking about.

**M**

I think that was exactly right.

**Deven McGraw - Center for Democracy & Technology – Director**

That was very well said, Terri. That's essentially what we intended here, and it's framed in the context that it's framed in, in order to permit some work to continue to go forward on NHIN Direct.

**Terri Shaw – Children's Partnership – Deputy Director**

Yes, and just to reiterate, part of the reason why this is really important for me to be clear on this point is because I want it to be – I want patients to have the comfort to know that their information is protected in the way that it's protected, regardless of whether that information is being sent electronically, by fax, by phone, by snail mail. It doesn't matter. It's being protected the same, regardless of the mode of transmission. And that's what we're talking about here is saying this new electronic mode of transmission doesn't change the underlying protections that exist.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. There is, to me, an analogy between NHIN Direct and the federated RHIO scenario that's for consumers. They need to understand that the difference is sort of like between the U.S. post office taking something and sending it to a receiver that's known versus a library where there are submitters of documents, and then you don't know who's coming in the door and what their authorization is or what their purpose is, and how do you establish how that kind of transaction happens.

**Terri Shaw – Children’s Partnership – Deputy Director**

Yes. I’m assuming that’s the second batch of discussion that we need to have.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. That’s exactly right.

**Terri Shaw – Children’s Partnership – Deputy Director**

Absolutely.

**M**

Right.

**Gayle Harrell – Florida – Former State Legislator**

This is Gayle. I’d like to add that in the transparency component of that direct ... the patient really should know that that information is being sent electronically.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie. I put this in my comments, but I think it’s important to note that regardless of consent, the law requires now, thanks to ARRA, that entities have the capability to account for disclosures. When you talk about transparency, I think you need to acknowledge that, by law, the fact that the exchange has occurred has to be transparent. So the question arises whether you are requiring that they tell them in advance, which is beyond, I believe, what’s in current law.

**M**

Dixie, you’re saying that an audit log for referrals, etc.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Well, accounting for disclosures is beyond audit logs. It’s more than, although audit contributes to it, audit is really what’s happening in a system. Accounting for disclosures is more an operational activity that accounts for it that says I shared this information with whom on what day and for what purpose.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. I....

**Gayle Harrell – Florida – Former State Legislator**

That exists now. You have to....

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Right, that’s in the law now.

**Gayle Harrell – Florida – Former State Legislator**

...now.

**M**

Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

So they already have the capability to tell a patient that this exchange occurred. By law, they have to be able to provide that. But there is no law that says they have to tell them in advance of these exchanges for treatment, payment, healthcare operations, and meaningful use.



**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Honestly, that would be entirely – this is John Houston. Trying to tell somebody in advance that that's going to occur is operationally, in my mind, impossible.

**M**

Right. I agree.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

I agree.

**Deven McGraw - Center for Democracy & Technology – Director**

This is Deven. On the accounting for disclosure law, the piece of that that falls down a little bit on the transparency point is that it's after the fact, and it's only if a patient asks for it. Having said that, I understand that a desire to be more transparent with patients about where their data goes, I'd like to see us address that in a broader context because it's part of fair information practice principles. Some of this notion of you don't need the patient's consent is based on an assumption that what we're doing here, at least with respect to much of the meaningful use transactions for treatment purposes, are consistent with patient expectations, but that's not always the case. And so we can certainly parking lot for further discussion, and we should, I think, have a more meaningful dialog about transparency with patients about how their data is used and disclosed. But it may be that we need to do so in the context of a more fulsome discussion on that topic. What do you all think?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**Gayle Harrell – Florida – Former State Legislator**

I think that needs to be discussed at length.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. Absolutely.

**Dave Wanser – NDIIC – Executive Director**

This is Dave. To me, the starting point is that patients own their data, and they should consent to its release. And we seem to have moved past that into some other areas that are certainly legitimate. But the bottom line is, the patients own their data and should consent to the release.

**Deven McGraw - Center for Democracy & Technology – Director**

But they don't.

**M**

But they don't.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

And they don't have to.

**Paul Eggerman – eScription – CEO**

Yes. This is Paul Eggerman. There's a form of electronic communication that occurs all the time, which is, physicians call each other on the telephone. That's electronic communication. The one doctor calls another and says, I've got your patient in the office, and I have a question for you. And they'll answer the

question. They just will. They assume the patient is there, and the patient wants to be treated, and you'll answer the question.

My observation, though, is that fundamentally I think we've made good progress by sort of drawing this line between the one-to-one where there's no intermediary that has the data, sort of like the analogy being to providers or providers speaking to an entity like a laboratory over the telephone, that that's sort of like a known series of issues. And there may be some other things about that that we want to talk about, versus the situation where you've got these RHIOs in the middle where there's basically an intermediary that has a copy of the data. That's a much more complicated consent situation that I suspect that Deven wants us to start to address.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

I have a question. This is Dixie. Both the policy and, well, primarily the policy committee has talked about that we anticipate that there will kind of be a cottage industry for these companies that would package these meaningful use reports and send them on to CMS, etc., which would, on the one hand, one could view as an intermediary. On the other hand, I suspect that in reality those will be business associates of the entities, and the law, as will an HIE, by the way, thanks to ARRA, and the law really doesn't, you know, it treats a business associate as a part of the covered entity. So if I send information to a business associate to package and send to CMS, under the law that doesn't require the patient's consent because that's my business associate.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Right. This is Kathleen. But they shouldn't be able to then turn those records over to the HIE that they're part of and have it used for exchange. So that's the kind of firewall, I think is the word.

**M**

The HIE is the business associate.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes, it's a business associate too.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

For the purposes....

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

...how to distinguish between those two....

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

...purpose ... the business associate cannot use the data for anything other than they are contracted to use it for.

**M**

Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Won't that be the case with an HIE?

**M**

Yes.

**Deven McGraw - Center for Democracy & Technology – Director**

I mean, it should be. But to be honest—this is Deven—we haven't received clarification yet on how the Office of Civil Rights is interpreting those rules, although I suspect that that's what will be in the rule that we're waiting for in that regard. But I also think that, in my view, that the HIE, the RHIO presents a slightly different scenario potentially as a business associate because, depending on how, we haven't had those in existence when business associates were first contemplated. And I don't think it would hurt for us to think about the ways that these RHIOs are being structured and processing data and how much they're retaining, and are they, you know, for some reason given independent rights to the data in some way, shape, or form. I think there's a whole lot that we don't know about it, which is one of the reasons why we've teed up those circumstances for greater focus with respect to consent or consumer preference, however you want to put it.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. I wonder if one approach is to think about the extent to which HIE activities varies from what was contemplated under HIPAA in terms of treatment, payment, and operation. If there's some variance there, then that might need to be looked at, and again, acting as a library where you don't know who is coming in the door to pick up the data sort of puts a very different spin on one provider giving information to another provider for purposes of treatment, etc.

**M**

I think that's all true. I mean, once you start to hold that data, I think Paul said it earlier well. Once you start to hold that data, you almost become a covered entity.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes, and maybe once we talk about HIEs, that seems to be a critical factor emerging here.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

But as a covered entity, they have to meet the purposes under HIPAA, and I'm not sure that the kind of exchange that's envisioned by HIEs in a noun sense come under those definitions.

**Paul Eggerman – eScription – CEO**

This is Paul Eggerman. The way I'm looking at the RHIOs and the HIEs, I'm looking at it from a consent standpoint as to like, if I'm the patient, why does somebody have my data? In other words, I wouldn't have any – I like the idea of what Deven said earlier, almost like implied consent. If I go to my physician, I get preoperative testing. There's an assumption there that that information is going to go to the hospital, and I know why it's going to the hospital. It's to treat me as the patient because I'm going to in the hospital soon, so that's the purpose of the exchange. And if it goes to a specialist, I know why it's there. It's to treat me as the patient.

The question is if I give consent for my data to go to a RHIO, you know, these health exchanges that store the data, what do I know about that? In other words, what am I consenting to?

**Deven McGraw - Center for Democracy & Technology – Director**

Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**Paul Eggerman – eScription – CEO**

To me, in my opinion, that's how we ought to phrase the issue. How do I get informed as a patient what I'm consenting to, and as long as I can understand that, then it's up to me to decide if that's really what I want to do.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. Paul, you didn't – under HIPAA, you didn't get a chance to consent. It was implied consent. I guess that's what you're saying. But did you imply in that consent that just anybody down the road can have access to that data based on some other episode of care, etc.

**M**

Well, but it's implied consent because it's going to another treating provider. This is going to the community.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Right. That's what I'm saying. I think I really like Paul's approach.

**M**

Yes. I mean, you can see, and I don't want to derail things here, but you can see what this is going to drive in terms of when it is held in the middle on consent or sending it in versus and/or consent for access.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**Deven McGraw - Center for Democracy & Technology – Director**

It sounds like we're starting to unearth some of the difficult issues that arise when you have these sort of networks or intermediaries in the middle, and not a lot of clarity about what they're doing. So let me, before we sort of continue to move down into and have a discussion about some of the issues that arise, I want to make sure that we are prepared to leave the earlier discussion and put it to bed. Of course, I'll reframe it in writing for us, for our next call, which, by the way, is next week, so everybody is comfortable with it. You'll have a chance to take potshots at it again.

But this notion that where we have existing law today, which covers the data sharing, particularly in the context of eligible providers and hospitals doing so to meet the stage one criteria for meaningful use, that we're not changing existing law with respect to patient consent, nor are we adding to it at this stage.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Only when it's direct exchange....

**Deven McGraw - Center for Democracy & Technology – Director**

Right, when there's no intermediary in the middle that is doing, you know, might have some access to that data beyond that's PHI.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

And capture Paul's point that intermediary not only has access, but keeps it, retains a copy of it. So it's not just a business associate that's doing something to it and repackaging and sending it on.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

This is John Houston. But there's nothing that prevents a business associate from holding data on behalf of a covered entity.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

That's true.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. I think we wanted to frame it in terms of that there is not an intermediary that provides a service beyond routing from one point to the other because we want to get to what we would do with intermediaries that do more than that.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

That was the point I was trying to make, and I probably didn't well. This is Dixie. A business associate is not an intermediary. That's treated in the law as the same as a covered entity. So if I send the data to a business associate who is providing me the service of packaging the data to send to CMS or to whomever within the context of meaningful use, that business associate is not an intermediary. That's a business partner of mine helping me do my meaningful use....

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. Clearinghouses, that would be a clearinghouse capability, and that's in a different position, and I'm afraid that opens the door to basically having HIEs as nodes in a transaction from one provider to another and skirting the kinds of constraints we might want to put on that scenario. So I would really like to see the HIEs limited to a node that only does routing, and that we're also carving out business associate type entities that maybe also doing clearinghouse capabilities.

**Judy Faulkner – Epic Systems – Founder**

This is Judy, and I have two questions.

**M**

Isn't a clearinghouse a covered entity?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes, a covered entity.

**Judy Faulkner – Epic Systems – Founder**

Can anybody hear me?

**Deven McGraw - Center for Democracy & Technology – Director**

Hold on a second. Judy has the floor.

**M**

Okay.

**Judy Faulkner – Epic Systems – Founder**

Thank you. I thought maybe my phone wasn't working.

**Deven McGraw - Center for Democracy & Technology – Director**

No, it's working.

**Judy Faulkner – Epic Systems – Founder**

Thanks. I have two questions. One, do we have a definition of business associate? In other words, I know a business associate might be across the street from me in a different organization, or we work together. But is a business associate also somebody who is in Florida and takes an individual who is a snowbird? Is that also a business associate? Number one. Number two, I like where we're going, and I do want to support Paul's question about the word push because technically it might be that a requesting organization asks for permission. The sending organization gives permission. And, at that time, permits the requesting organization to pull, and so it could be done either way technically, and it might cause confusion to use just one.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**Judy Faulkner – Epic Systems – Founder**

Those are my two comments.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, that's fair. Judy, there is a definition of business associate, and it's an entity that performs a function on behalf of a covered entity using PHI that it gets from that covered entity for the specific purpose of performing that function.

**Judy Faulkner – Epic Systems – Founder**

That sounds pretty good. Some of our customers are just putting a statement out saying we will share your data with everyone who is needed to contribute to your care, and that's their statement that they make. I don't know whether that means that the patient is notified or not, but I like the idea that as long as you're providing care for the patient's health, the fact that the patient has to be notified in advance isn't required.

**M**

That's the definition of a healthcare provider. You look at the definition of healthcare, and then you look at the definition of provider, and it really, as opposed to a business associate, which is somebody – it really comes down to whether somebody is providing care to the patient, or whether they're providing some type of administrative or backend service to the covered entity that is in turn providing the services to the patient.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. Our capabilities who are entities who are not direct care providers to ... exchanging data for or sharing data for treatment, for example, say SureScripts who is bundling up medication histories, that could be, they might be claiming that they're doing this for treatment. So I think we need to draw a fine line there. And the last thing I would like to say is, whatever we come out of this with, please let's make sure that the recommendation says we expect the EHR technology to support the currently required consent and authorization where those are needed.

**Terri Shaw – Children's Partnership – Deputy Director**

Here, here. Terri Shaw. I agree.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie. I think that we have to allow for the case in which, especially for small providers, they use a business associate to help them do some of this reporting. I think that the idea that you can't even – you've got to allow that because it's going to happen, and everybody is assuming it's going to happen.

**Deven McGraw - Center for Democracy & Technology – Director**

I think that's fair. What if I take the obligation to try to craft something that's more particular that addresses this notion of, you know, our legitimate concerns about sort of middlemen, RHIOs, and HIEs, but doesn't trip up this idea that business associates may be utilized under current law to perform some of these functions and are held accountable for what they do with data when they do so.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes.

**Deven McGraw - Center for Democracy & Technology – Director**

All right. I will take that on. These comments have all been incredibly helpful, as usual. One of the things, as we move into the next phase of the discussion, you all will recall on our last phone call, or maybe you won't—it was like three weeks ago—that we had a very brief presentation of slides from the two folks who have been drafting a paper for ONC that does cover some of the different network models that are out there, and it looks like, at our next meeting, which is next week, we can actually start with a chance to get more details about that paper. Jodi, Joy, Sarah, are we going to get to read that ahead of time, or what can the workgroup expect with respect to getting more information about that research that was done on consent and these networks, etc.?

**Joy Pritts – ONC – Chief Privacy Officer**

This is Joy. It's my understanding that that paper should be available of you early to mid next week.

**Deven McGraw - Center for Democracy & Technology – Director**

Okay.

**Jodi Daniel – ONC – Director Office of Policy & Research**

Then I think that we're going to try to have the folks who were the authors of the paper participate in the call or at least get one of them to participate in the call, and they'll probably put together some brief PowerPoints as well, and we'll make sure to get those out to the group in advance as well. But we'll try to make sure folks have time to look at the paper so that they can ask questions and be able to think through the issues based on some of the information that's presented in there.

**Deven McGraw - Center for Democracy & Technology – Director**

Can you say again more specifically what the topic of the paper was because I'm not sure I hit it squarely on, or maybe I did.

**Jodi Daniel – ONC – Director Office of Policy & Research**

I guess I'll jump in. This is Jodi again. The goal here was to look at consumer choice, issues related to consumer choice, basically in the context of networks, although we've kind of asked them to be a little bit broader than that and just identifying various options and approaches for dealing with consumer choice and consent. And then looking at it from a variety of different perspectives, so they've looked at it from different stakeholder perspectives and some of the challenges or preferences, the different stakeholders bring to the issue. They've looked at it from the standpoint of some of the different disciplines, so based on the legal landscape, ethical obligations, human factors, how much choice, you know, based on some research on how consumers process a variety of choice options. So they've tried to look at it from a lot of different perspectives.

We asked them not to come up with recommendations because we wanted this to basically be a comprehensive piece that brought together all of the issues that surround looking at consumer choice

models in the context of health information technology and health information exchange, but to leave the thinking and the discussion and the recommendations hopefully to you all, and then ultimately to ONC to try to come up with some policy in this area. So the goal is really to kind of tease out a lot of the issues and bring up some perspectives that people might not be thinking about in trying to analyze what the right, you know, what some recommendations might be for policy in this space, understanding that things have changed since this HIPAA rules were drafted, and looking at some of those changes. Does that help? Joy or Sarah, do you have anything else to add to that?

**Joy Pritts – ONC – Chief Privacy Officer**

Sounds right.

**Sarah Wattenberg – ONCHIT – Public Health Advisor**

No, it sounds like what the paper was supposed to cover.

**Jodi Daniel – ONC – Director Office of Policy & Research**

And there's a lot in there about examples of what HIEs are doing, so folks have a sense of sort of the landscape, as well as some international examples. So it really tries to pull together a lot of information in one place to help people think through this.

**Deven McGraw - Center for Democracy & Technology – Director**

Terrific. What I had done with this outline that I circulated was to start to come up with some questions to consider, as we do start to tackle this issue of the RHIOs and the HIEs and whether there ought to be an additional level of consent beyond what's already required in law when those are used. We've just started to uncover some of them, one of which is what defines a network or HIE for which some additional choice requirements might be required.

Does it hinge on some of what we've talked about on the call today, this notion that there's an ability for that network to somehow hold data or see data or use data versus just being a conduit from one endpoint to another? How would you slice those choices? If you were to give them, would they be imposed as requirements or recommendations? And if they're requirements, what do we do about HIEs that haven't approached this issue and have instead focused more on limiting the purposes for which the HIE can be used, such as just treatment and public health? Where does the choice get applied? This is the point that, John, I think you've made on numerous occasions, both with respect to the upload, as well as the download. And to what extent do the different purposes for which the data can be accessed through a network, to what extent does that matter and change the extent of the choice conversation?

And so I think we can start to have that discussion. It sounds like the paper might give us a whole lot more information from which to draw, but I'd love to start talking about it now if you think we're ready. But if folks would rather wait until they see the paper, I'm comfortable with that as well.

**Gayle Harrell – Florida – Former State Legislator**

I would prefer to wait for the paper.

**Deven McGraw - Center for Democracy & Technology – Director**

You want to wait for the paper.

**Paul Egerman – eScription – CEO**

This is Paul Egerman. I'm sort of neutral on whether or not ... paper. I'm willing to do it either way. But I would just frame the questions differently thought. I mean, the document uses this expression pull for the data.



**Deven McGraw - Center for Democracy & Technology – Director**

Yes, I'm stuck on that push/pull. I stand corrected on that by both you and Judy. But just so you understand what was in my head when I used it, I have this vision of participants in a network being able to sort of, by query of a data, you know, by patient name for example, being able to access data in another provider's record. It could be for treatment purposes. But in other words, they can get it electronically. It's not in their record, and they query it. And again, depending on sort of what the process is, it might not necessarily be independently pushed in response to that query.

But this ability to sort of go in and query a patient and pull data out of a record that isn't yours, and where you don't have that circumstance where the patient has some implicit knowledge, either expressed or implicit knowledge or expectation that that's happening, we sometimes refer to this as fishing expeditions. So it's not always fishing. There might be in fact quite legitimate queries going on, but I have always had as a sort of gut reaction over the past year or so when this stuff has become more prevalent that that creates a scenario for which we probably should give patients some right to choose about whether their data can be accessed in that way.

**Paul Egerman – eScription – CEO**

Sure. This is Paul Egerman. Just to sort of follow up on my comment because not only do I have an issue with push and pull, but I also have an issue with the word network, which means a million different things.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, I know.

**Paul Egerman – eScription – CEO**

The way I would frame this a little bit differently would be to say, if you have this intermediary, this RHIO, who are like the—I don't know what the right word is—they participants, the authorized members, the people who are the entities who have access to the data? If I'm a patient, who are the entities who can have access to the data, and for what purposes do they have access to the data? It would seem to me, those are the things that need to be disclosed to the patient, so they can make an informed decision as to whether or not they want to give consent.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

This is John Houston. I think there's some fundamental – I hate to use this word naivety here, but I think we have to be incredibly concerned about the idea of volume, and as we move progressively towards more and more interoperability and exchange of information is how do we try to handle the incredible volumes of requests and exchange of information that's going to occur, and is it practical to think that there's going to be reasonable processes in place to get patient consent?

I'm going to get on my soapbox for a second, and Deven is probably going to strangle me, but I keep going back to this. There has to be some level of governance in whatever we do because I think what's got to happen is there's going to have to be some way to enforce good conduct by providers as a surrogate for....

**Deven McGraw - Center for Democracy & Technology – Director**

I didn't hear your last point, John. That was either you or somebody else on the phone.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

I think we're going to need to have some level of enforcement and governance as a surrogate for patient consent because I don't think patient consent is going to hold up under volume.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen ... I would disagree. There are ways to do that.

**Deven McGraw - Center for Democracy & Technology – Director**

Who just called my name?

**Rachel Block – New York eHealth Collaborative – Executive Director**

It's Rachel. It's a great discussion, so I really didn't want to interrupt, but I just wanted to, regarding the last two points, and if we're going to defer the discussion, that's fine, but those are exactly the kinds of issues that we tried to address in the model that we have in New York in terms of spelling out the roles and responsibilities of different entities, how governance how plays into that. I would offer, John, that as a practical matter, we haven't had any problems whatsoever in terms of handling the volume of patient consent so far, and we have a pretty robust operational HIE now occurring on a statewide basis in New York, so we can also share some practical information with you about how it's working in the current environment. But I did want to just mention that many of the issues that you both touched on are specifically addressed in that PowerPoint.

**Judy Faulkner – Epic Systems – Founder**

This is Judy. Our customers have a bit of a different experience than yours. We've finding a number of customers who are saying that they're going to be inundated by volume if the patient has to consent each time, and that especially if they have to ... copies, which I think some state laws may say that they just can't deal with that. And so they have not moved to doing interoperability because of their fear of volume.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. Is that the EHR itself or the HIE, because I think Rachel....

**Judy Faulkner – Epic Systems – Founder**

It's the EHR. It's direct exchange.

**Rachel Block – New York eHealth Collaborative – Executive Director**

Yes, I was talking about the network or HIE model.

**Judy Faulkner – Epic Systems – Founder**

Yes, and that's a good point because it means it might not be going both ways. It may be applicable to one, but not the other.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie. I think one factor that will play a big role in this and that certainly we need to address is the persistence of the consent and the responsibility for persisting consent with the data, as it moves across the network, and if a patient changes their mind, the responsibility for tracking down all instances of their data and making sure that consent gets propagated. Those kinds of things, I think, would really have a huge impact, as volume increases.

**Michael DePalo – BCBC**

This is Mike DePalo. I think you also might need to think about granularity. I don't know what degree the New York model requires different consents for different types of disclosures. But if you're monitoring blanket consents for broad types of disclosures ... volume, as well as the applicability, versus giving the

consumer more specific control over their information, where it goes, how it's used, and what information is disclosed and used.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. Mike, this is Deven. We had initially, on our last call, agreed to try to take this in two slices, which would be macro consent. Actually, I think we called it course consent, but I decided I liked the word macro better, and whether that's all in or all out, or maybe one more level down, which is all in by institution or provider organization, or all out, versus by the data type. But we did want to get to the more micro piece of by data type, and then how you would honor that, understanding all along that there are different technical challenges that are raised by these different levels, and we need to have as clear an understanding as we possibly can about sort of what's the state of the technology today and where it's headed in the very near future, so that when we make our policy recommendations, we're not either overshooting or undershooting what we're asking for.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

After seeing the New York HIE presentation, it's almost as – I don't see any particular benefit in dividing this. Can you explain again why we would want to do that?

**Deven McGraw - Center for Democracy & Technology – Director**

Well, I think, and I don't know how many folks have had a chance to look at that slide deck since it's most relevant to the more – but the conversation we started to engage in on this call, and that we will continue on the next call. So if you haven't and a chance to read through it, you should. It's an interesting illustration of one state's approach to this. And they didn't go down to the granular level, and I suppose it's possible we could decide that we wouldn't recommend going there as a group, but just because they didn't, I'm not sure that that....

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

...that they didn't ... I thought they had a course, and they did have some granular choices at some points in it. I thought they had a mixed bag. Maybe I....

**W**

The choice is relative to which providers have access. It's an access model, so it's consent at the point when a provider wants to access information. And the choice relates to whether you want to authorize one provider to have access to that information or multiple providers based on relationships that you might have with other providers. And we do specify that you have to have the ability to identify which providers would have access, but it is not course or fine in terms of the types of data with respect to the types of data. It's all in or all out.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

All right.

**W**

That just happens to be how we're doing it now. I want to just emphasize, we wanted to share this with you because it was a way of thinking through the questions, not so much because we want everybody to agree with our approach.

**Michael DePalo – BCBC**

Let me make sure I'm clear about this. This is Mike DePalo. Let me make sure I'm clear about this. Your approach is that if I'm the patient, and I give my cardiologist permission to request information, he can get that information and any other information about me, whether or not it's related to my cardiology problem?

**W**

Yes.

**Michael DePalo – BCBC**

Okay.

**M**

I would call that macro.

**W**

Yes.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

But in theory, under HIPAA—this is John Houston—even though a provider is entitled to rely upon the request of another provider in terms of what information that provider needs, I mean, I think there's still some idea that providers really should only request that which is necessary.

**W**

That's right.

**W**

This doesn't allow a requesting provider to limit it, really. They get at everything, whether they want it or not.

**M**

No, I think John's right. The provider that is giving the information is subject to minimum necessary under HIPAA as well, to make a known decision about whether or not that should be disclosed.

**W**

Do we want that to follow through on the HIEs as well? I mean, HIEs are not doctors.

**Joy Pritts – ONC – Chief Privacy Officer**

No. I need to interrupt you. This is Joy. Minimum necessary requirements do not apply to disclosure or requests to another provider for treatment purposes.

**M**

No, but what HIPAA does say thought is, again, a provider that has a record is entitled to rely upon the requesting provider as to what that requesting provider needs in terms of information in the record.

**Joy Pritts – ONC – Chief Privacy Officer**

Yes.

**Paul Eggerman – eScription – CEO**

This is Paul Eggerman....

**M**

But there's a corollary to that, which is, in theory, a provider is not expected or should not be requesting the entire record if that provider doesn't reasonably believe that it needs to have access to the entire record.

**W**

Yes. They're encouraged to take that approach in the guidance. That's exactly right.

**Paul Egerman – eScription – CEO**

Yes, but this is Paul Egerman. A practical issue is the IFR really only, I guess it provides two mechanisms to exchange records data. One is called CCD. The other one is called CCR. I mean, so in terms of providers exchanging data, you've got to take whatever is in that CCD. That's how you get your data. You can't just say I just want this one single medication and the dose on this medication because they don't have a mechanism to give you that. They have to give you the entire medications list and the entire diagnosis list and everything else that's in the CCD because that's the only interface things that we're specifying. If we want more granularity, we can ask for stage two to add more granularity on the interfaces, but that's not what exists right now.

**Deven McGraw - Center for Democracy & Technology – Director**

Well, right, and that's with respect to meaningful use transactions. But certainly, through other mechanisms, even non-electronic, quite frankly, or by fax or by phone, free pieces of data could still flow.

**Paul Egerman – eScription – CEO**

Sure.

**Deven McGraw - Center for Democracy & Technology – Director**

But it's a good point to remember that we actually created some specific constructs for the movement of certain types of data or forms or reports.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. You can put marks, the different sections in a CCR according to policies that you might have. For example, if an HIE said that only certain kinds of providers could have access to lab or medications that had a value of an HIV, that could be marked in the CCR/CCD when it was deposited in the HIE, and that could be used to offer a more fine grained access and limit the provider's access to data they shouldn't or may not want. You can do it section by section.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Given that the application at the receiving application can interpret them.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Well, the HIEs could have the mechanism for just sending or basically rejecting those sections and sending out a CCR or a CCD that was missing that data. So basically making a copy without those sections in it and sending it to the provider. The provider doesn't have to do anything.

**Paul Egerman – eScription – CEO**

That's helpful. You can do it by sections, or you can actually do it by item?

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Not in this current CCD standard. You can in the CCR. Again, the first meaningful use documents will probably not be the only ones. There will probably be different profiles, and one of the things that this committee could do is say, we'd really like to see the standards adopted that give more, the ability to tag these documents at lower levels. The underlying standard, which is VA, doesn't preclude marking it down to the ... for the CCD. It doesn't preclude marketing it down to a much lower level.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

If we wanted, like to me, it makes sense for an HIE to have a requirement that they be able to interpret those restrictions that are within the CDA or CCD document. What would be the mechanism for even getting? I guess it would start with us defining a policy that HIEs should be able to do that. Deven, this is a really a question, I guess, for you and Jodi, maybe. If we thought that that was a good idea, could we establish policy that HIEs be able to interpret and enforce those restrictions?

**Deven McGraw - Center for Democracy & Technology – Director**

We, of course, can't establish any policy.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

I know, but recommend.

**Deven McGraw - Center for Democracy & Technology – Director**

We can only make recommendations to the policy committee, which would then have to deliberate them. I think it's a little bit down in the weeds, although we might get to that point. So if you're asking theoretically whether it's possible for us to make a recommendation on that point, yes.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Yes, I was really thinking because it's outside....

**Deven McGraw - Center for Democracy & Technology – Director**

Prepared to do that, it seems a little down in the weeds in my view, but...

**Paul Egerman – eScription – CEO**

This is Paul Egerman. Even getting back to Kathleen's comments, while that's theoretically possible for an HIE to do that, that's not what the IFR says.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

It doesn't address HIEs. It addresses EHRs. That's really the....

**Paul Egerman – eScription – CEO**

If I could just finish, what I was trying to say, it's not what the IFR says. If I'm a physician and buy a certified EHR from a vendor, it's going to have a capability to send out a CCD or a CCR. It's not going to have the capability Kathleen just said.

**W**

Right....

**Paul Egerman – eScription – CEO**

...getting back to this issue of granularity. There's really not a way for most providers to provide that level of granularity. Their software won't do it.

**W**

Paul, if those EHRs are certified to emit a compliant CCR or CCD, then they can have that capability in the EHR.

**Paul Egerman – eScription – CEO**

How?

## W

Because a compliant CCD can do these things. It can put a confidentiality code in those sections, and a CCR can too, and a confidentiality code can reflect the type of sensitivity of the data, and then the HIE can treat it appropriately.

### **Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Well, but only, I mean, putting the confidentiality code in there is a semantic kind of a thing, but the capability for an EHR to actually process those and enforce the rules associated with those confidentiality codes would require the EHR to have that as a certification criterion.

### **Deven McGraw - Center for Democracy & Technology – Director**

I'm just going to stop the conversation because it's going way down into a level of detail that I don't think we need to get to, at least at this point.

### **Terri Shaw – Children's Partnership – Deputy Director**

Although, Deven, this is Terri. Can I just jump in for a second? I do think that the important thread that's coming through here is a linkage that says, in this first bucket of consent rules that we talked about, which is basically current law, we noted and EHRs should be designed and certified to assist in doing that consent management, if you will.

### **Deven McGraw - Center for Democracy & Technology – Director**

Right.

### **Terri Shaw – Children's Partnership – Deputy Director**

I think the same is – I think what we're basically saying is the same thing on the HIE side. When we get into the world where we're talking about HIEs, we want to make sure that the HIEs have that ability to manage proper, not only consent management, as in knowing what's consented to or not, but actually controlling the flow of information in accordance with whatever the consent is. I think, on a macro level, so to speak, without getting into the weeds, that's the principle that we're trying to get to, which I agree with, although I will say immediately to me what comes to mind is the question then of whether if an HIE provides a consent management service, whether we think it's okay for a provider to rely on whatever determination the HIE has made or assertion that they have as to consents that are in place as meeting their obligations for managing consent and authorization requirements. That's a flag for future discussion, but I do think the principle of wanting EHRs and HIEs, as appropriate, to build in the technology to support consent management and compliance is something this group wants to weigh in on.

### **Deven McGraw - Center for Democracy & Technology – Director**

Yes. One of the things that I'm also hearing in this thread of conversation, in a broader context, is a recognition that while these consent issues that were taking on with respect to HIEs, intermediaries, I'm going to try not to use the term networks, are critical, we're also recognizing that there are all these other policy issues. I think Paul Eggerman, I think it was you who said consent to what. Like, you know, for what purposes? Who has access to it? For what purposes can the data be used? What functionalities are HIEs expected to take on? And how can we enforce whether they're doing that or not?

There's a whole constellation of things that come into place, and a lot of unanswered questions here, which we can certainly put, I think, and should put recommendations forth, even as we're tackling some of these consent issues. Again, we're not dealing with this in a vacuum, although it's a big nut to crack, I think. It's a challenge to figure out where to start with these things. Does that make any sense? I mean, I sort of see a whole constellation of issues. I mean, notwithstanding that HIEs and RHIOs were deemed to be treated as business associates under HIPAA under the HITECH Act. As I said before, and I sense

that at least there are some folks on the phone who agree with me. I don't think that answers very many of these difficult questions.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

This is Kathleen. Is it possible to request some help from, I don't know if there are resources to do things like other white papers or retain folks who can go and look at answers to specific ones of these questions and present it in a way that's at a level that's appropriate for our discussion.

**Deven McGraw - Center for Democracy & Technology – Director**

I think so. We'll get that white paper, which will, I think, probably address some questions.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**

Not the technical stuff.

**Deven McGraw - Center for Democracy & Technology – Director**

But not the technical stuff, yes. I mean, I think, to the extent that there are technical issues that we need some input on in order to reach some policy decisions, I would hope that we could get assistance. Joy, Jodi, Sarah, any thoughts about that?

**Sarah Wattenberg – ONCHIT – Public Health Advisor**

Yes. As the need arises, it would be useful, as we go along, to kind of make a list of the issues where you think you'll be needing more technical assistance, so that we can try to get that lined up.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

This is Dixie. As you know, Deven, the standards privacy and security workgroup has started a series of educational sessions on various standards that relate to consent, and I think it's kind of important that we keep those two, as we've discussed, separate, you know, separate but complementary.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. We certainly don't want to. I mean, I have no interest, as a policy person, in deciding which standard ought to apply. But it becomes relevant to us, I think, because we certainly don't want to be dictating policy for which there aren't good technical standards or functionalities to achieve it.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

I'm planning one of those sessions to be addressed on exactly the issue of the HL-7 confidentiality codes and the CCD standard. Maybe what we could do is, well, we should discuss this, but we could potentially consider having both groups participate.

**Deven McGraw - Center for Democracy & Technology – Director**

That's a public hearing, right?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

No.... It's a public meeting, yes. It's a public meeting.

**Deven McGraw - Center for Democracy & Technology – Director**

Public meeting, so perhaps we can. I mean, I know I got a courteously invite, but we should, if possible, extend that to the other members of the workgroup who would like to participate.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Yes, I can do that. It's Judy.



**Deven McGraw - Center for Democracy & Technology – Director**

That's great, Judy. Thank you. What I'm going to encourage folks to do is, we'll get you that paper as soon as we're able to, early to mid next week. But in the meantime, if I can give you a little homework, and to start, I mean, again, I put a list of questions to consider, including, you know, it's a little bit of a who, what, when, where list. But if you think of others, and start sketching out some pathways to beginning to draw some conclusions, and I'll be doing the same. We have very little time between now and our next call, which is—

**W**

It's the 25<sup>th</sup>.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, the 25<sup>th</sup> at 2:00 eastern time, which is next Thursday. Then we have a little bit more breathing space before the next one, but we essentially have two calls between now and the April policy committee meeting to make some more progress on this. We did actually make more progress than I thought, and mostly because we are anxious to devour some more information before diving into this issue further. It makes sense for us to open the call up to the public.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Okay. Operator, do you want to open the line, please, to see if we have anybody from the public that cares to make a comment?

**Operator**

No public comments as of yet.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you. It's Friday.

**Deven McGraw - Center for Democracy & Technology – Director**

It's Friday, and it's a nice day, and we'll be, again, continuing at least the sort of HIE part of this conversation next week. Also, as I promised, I will reframe the conclusions we drew in the beginning part of the call to make sure everybody is comfortable with them. Is there anything else? We can let everybody go early.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Yes. That's great. Thank you.

**W**

Terrific.

**Deven McGraw - Center for Democracy & Technology – Director**

You were right, Judy. This was a relatively short call.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Quick, yes.

**W**

Not quick.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you, everybody.

**W**

...Friday afternoon with sunshine would end the conversation early.

**M**

Thank you.

**W**

Bye.

**M**

Bye-bye.

**W**

Bye.